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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,558	10/20/2000	Elfi Biedermann	25846-0003	7777

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EXAMINER
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SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/693,558

Applicant(s)

Beidermann et al.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32-52 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 32-52 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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Applicants' timely filed response to the last Office Action on October 10, 2001, Paper No. 11, is acknowledged. New claims 50-52 are presented. Accordingly, claims 32-52 are now under consideration.

Upon reconsideration a requirement for restriction is deemed proper. At the discretion of the Examiner, a restriction requirement may be made at any time during prosecution before final action in the case, 37 C FR 1.142. All arguments presented by Applicants in Paper No. 11 will be fully addressed in the next Office Action.

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 32-40 and 50, drawn to methods for preventing, reducing or eliminating side effects or neutralizing the side effects of a cancerostatic or immunosuppressive agent comprising administering a compound having vitamin PP activity of formulae II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va or Vb, wherein no heterocyclic ring systems or sugars are present, classified in Class 514, subclass 318.
- II. Claim 32, 33, 38-40 and 50, drawn to methods for preventing, reducing or eliminating side effects or neutralizing the side effects of a cancerostatic or immunosuppressive agent comprising administering a compound having vitamin PP activity of formulae IV, IVa, IVb, wherein a heterocyclic ring system is present.

*mutually exclusive*

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drawn to various subclasses of Class 514, depending of the heterocycle contemplated.

III. Claim 32, 33, 38-40 and 50, drawn to methods for preventing, reducing or eliminating side effects or neutralizing the side effects of a cancerostatic or immunosuppressive agent comprising administering a compound having vitamin PP activity of formulae IV, IVa, IVb, wherein a sugar moiety is present, classified in Class 514, subclasses 23.

IV. Claim 32, 38-40 and 50, drawn to methods for preventing, reducing or eliminating side effects or neutralizing the side effects of a cancerostatic or immunosuppressive agent comprising administering a compound having vitamin PP activity, that is not encompassed in any of the other groups recited *supra*, classified in various subclasses of Class 514, depending on the compound having vitamin PP activity contemplated.

V. Claims 41-49, 51 and 52, drawn to pharmaceutical compositions comprising a compound of instant formula I, optionally in combination with a compound having vitamin PP activity or a prodrug thereof and at least one physiologically acceptable carrier, classified in class in various subclasses of 514, depending of the particular compounds contemplated.

Additionally, claims 41-49, 51 and 52 are generic to a plurality of disclosed patentably distinct species comprising various compounds of instant formula I, optionally in combination

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with a compound having vitamin PP activity, as disclosed throughout the subject specification. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

The Groups have acquired a separate status in the art as shown by their different classification and their recognized, divergent subject matter. The searches required for each group are not co-extensive. Each group is capable of supporting a separate patent. The large number of structurally unrelated compounds presents an undue burden. Thus, restriction for examination purposes, as indicated, is proper.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are advised that to be complete, the reply to this requirement must include an election of the invention to be examined even though the requirement is traversed (37 C.F.R. 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(I).

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

January 2, 2003

*Phyllis Spivack*

**PHYLLIS SPIVACK**  
**PATENT EXAMINER**  
**GROUP 1614**